UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,790	01/14/2002	Richard A. Rosenbloom	QUIG-1006CIP	3053

21302 7590 09/23/2003

KNOBLE & YOSHIDA
EIGHT PENN CENTER
SUITE 1350, 1628 JOHN F KENNEDY BLVD
PHILADELPHIA, PA 19103

EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	**PAPER NUMBER**
1617	15

DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Applicati n No. 10/045,790	Applicant(s) ROSENBLOOM, RICHARD A.	
	Examiner Shaojia A Jiang	Art Unit 1617	

--The MAILING DATE of this communicati n appears on the cover sheet with th correspondence address --

THE REPLY FILED 02 September 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attachment*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *none*.

   Claim(s) objected to: *none*.

   Claim(s) rejected: *1-20*.

   Claim(s) withdrawn from consideration: *none*.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

SREENI PADMANABHAN
PRIMARY EXAMINER 9/22/05

Advisory Action

This Office Action is a response to Applicant's amendment and response after FINAL filed on September 2, 2003.

2. The declaration of Dr. Anthony W. Addison (not inventor) submitted September 2, 2003 in Paper No. 14 under 37 CFR 1.132, is acknowledged and will be further discussed below.

Applicant's proposed amended claims are not deemed to place the application in better form for appeals by materially reducing or simplifying the issues for appeal.

5. Applicant's remarks and the declaration of Dr. Anthony W. Addison filed September 2, 2003 regarding the rejection of claims 1-20 made under 35 U.S.C. 112, first paragraph for lack of scope of enablement have been fully considered but are unpersuasive for reasons of record in the Final Office Action March 26, 2003.

It is noted that this rejection is made under 35 U.S.C. 112, first paragraph for lack of scope of enablement, **not** made under 35 U.S.C. 112, first paragraph for lack of "Written Description". Thus, Applicant's argument in the remarks and declaration regarding the "Written Description Guideline" has been considered but not convincing.

Applicant also asserts that "the tests that are well-known to persons of skill in the art for determining whether a particular compound inhibits cell differentiation or cell proliferartion". However, as discussed in the Final Office Action, *Genentech*, 108 F.3d at 1366, the court states that "a patent is not a hunting license. It is not a reward for

search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable". Moreover, as a result, necessitating one of skill to perform an exhaustive search for the embodiments of any compounds having those functions recited in the instant claims suitable to practice the claimed invention with ***undue experimentation***.

In response to the list of the anti-inflammatory drugs approved by FDA in Applicant's argument and Exhibit L, note that the instant claims are not limited to those anti-inflammatory drugs approved by FDA. Moreover, it is noted the instant claims are not limited to those known antioxidants and antioxidant enzymes as Applicant argues.

Further, as discussed in the Final Office Action, one of skill in the art would recognize that it is highly unpredictable in regard to therapeutic effects, side effects, and especially serious toxicity that may be generated by drug-drug interactions when and/or after administering to a host the ***combination*** of any compounds represented by "one or more compounds effective to regulate at least one of cell differentiation and cell proliferation", "one or more antioxidants", and "one or more antioxidant enzymes", and "anti-inflammatories", which may encompass more than a thousand compounds.

Therefore, in view of the *Wands* factors, the case *University of California v. Eli Lilly and Co.* (CAFC, 1997) and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in ***undue experimentation*** to test all compounds encompassed in the instant claims and their

combinations employed in the claimed compositions to be administered to a host, with no assurance of success.

Applicant's remarks and the declaration of Dr. Anthony W. Addison filed September 2, 2003 regarding the rejection of claims 1-20 made under 35 U.S.C. 112, second paragraph, for indefinite recitations, have been fully considered but are unpersuasive for reasons of record in the Final Office Action March 26, 2003.

Again, the recitations "one or more antioxidants" in claim 1, "structurally similar derivatives thereof which exhibit antioxidant activity" in claim 4, and "one or more antioxidant enzymes" in claim 6, and "anti-inflammatories" in claim 12, and "compounds containing selenium" in claim 10 render claims 1-20 indefinite since one of ordinary skill in the art could not interpret the metes and bounds as to the recitations herein. It is noted the instant claims are not limited to those known antioxidants and antioxidant enzymes. Therefore, the scope of claims is indefinite as to the composition encompassed thereby employed in the claimed methods, as failing to clearly set forth the metes and bounds of the patent protection desired.

Applicant's remarks filed September 2, 2003 with respect to the rejection of claims 1-20 made under 35 U.S.C. 103(a) as being unpatentable over KITA, K (WO 9718817, equivalent to 6,162,801), and Bissett et al. (of record) and Darr et al. (of record) in view of Shimoi et al. (of record) and Kim et al. (5,776,460, of record) have been fully considered but are unpersuasive for reasons of record stated in the Final Office Action dated March 26, 2003.

As discussed in the Final Rejection, the motivation to combine the teachings of the prior art cited herein to make the present invention is seen. The claimed invention is clearly obvious in view of the prior art.

As also indicated in the Final Rejection, the record contains no clear and convincing evidence of nonobviousness or unexpected results for the oral compositions herein employed in the claimed method herein over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. A. Jiang, Ph.D.
Patent Examiner, AU 1617
September 22, 2003